Clinical Medicine

Evaluation of the First 300 Patients Treated at an Outpatient Center for Male Sexual Dysfunction

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A comprehensive multidisciplinary evaluation was carried out on 300 outpatients seen consecutively at a specialized impotence center. Psychologic evaluation was coupled with the use of contemporary diagnostic modalities. Nocturnal penile tumescence testing, penile vascular studies, pharmacologic diagnostic testing and dynamic infusion cavernosography have been used advantageously. In addition to psychologic counseling for all treatment categories, treatment alternatives have included hormonal and pharmacologic agents and penile prosthetic implantations.

(Ellis LR, Nellans RE, Kramer-Levien DJ, et al: Evaluation of the first 300 patients treated at an outpatient center for male sexual dysfunction. West J Med 1987 Sep; 147:296-300)

Increasingly, urologists are becoming the primary source for information and treatment regarding impotence. But the typical busy urologic and general medicine practice setting does not lend itself well to the measured evaluation necessary for optimally managing this problem. An awareness of the promising alternative of multidisciplinary impotence treatment centers elsewhere led to the establishment of the Northwest Center for Impotence in October 1984. We present the results of the diagnostic evaluations and therapeutic techniques used with 300 outpatients evaluated consecutively at the center since its inception.

Methods

The center was initially conceived as a collaborative venture, embracing both urologic and psychologic disciplines to provide case-specific treatment plans. An exceptionally well-qualified registered nurse coordinator was recruited, and provisional agreement was subsequently achieved among urologists and two groups of certified sex therapists. Initial patient contact with the nurse coordinator to outline the purpose and overall management approach has been pivotal to successful clinic efforts. Comprehensive patient education and an awareness of support services have been achieved. Instructional videotape material has been used extensively throughout diagnostic and treatment phases. Clinic urologists have employed cost-effective, focused diagnostic testing followed by the institution of selected medical or surgical therapies or referrals for appropriate counseling.

Initially, a separate physical location was considered desirable to provide the most confidential patient care setting. After 18 months of free-standing operations, however, subsequent disadvantages were not noted with reconfiguration into a full-service urologic office suite.

The center's development also involved the establishment and ongoing coordination of an impotence support group in collaboration with the local hospital. Monthly meetings have been held with both patients and partners attending either confidential, closed group sessions or public forums featuring selected speakers. Increased public awareness and acceptance have evolved.

General Evaluation

After first reviewing the extensive preliminary patient questionnaire, clinic urologists take a comprehensive history and do a physical examination with special attention to cardiovascular, neurologic or psychosexual disorders. Laboratory evaluations including blood glucose, luteinizing hormone, prolactin and testosterone levels focus on endocrinologic manifestations such as diabetes mellitus or disorders of gonadal function. The laboratory screen also evaluates renal, liver and thyroid function.

Special Vascular Testing

In addition to a careful vascular history and physical assessment, the noninvasive Parks vascular minilaboratory apparatus with a 9.5-mHz Doppler probe has been used extensively. A consistent and reproducible measurement of the penile pulse volume, with Doppler and photoplethysmographic systolic occlusion pressure testing, has provided an accurate evaluation. Normal ratios of penile artery to brachial systolic occlusion pressures (penobrachial index, or PBI) are defined as greater than 0.75; PBI values of 0.72 to 0.75 are borderline, and less than 0.72 are considered abnormal.²⁻⁴ When arterial or venous lesions have been suggested by noninvasive test results, an evaluation protocol has been used (see Figure 1) for further confirmation. Papaverine diagnostic screening has been used judiciously, usually involving the intracorporeal administration of 1 ml of a standardized papaverine-phentolamine mixture containing 30 mg papaverine hydrochloride and 0.83 mg phentolamine mesylate. 5 Selected patients with possible arterial lesions or the pelvic steal syndrome have been evaluated by phalloarteriography. Patients with an adequate arterial inflow and adequately achieved but poorly sustained erections have also been studied by dynamic infusion cavernosography to evaluate a possible venous insufficiency.6 Cavernosography in the normal flaccid state reveals

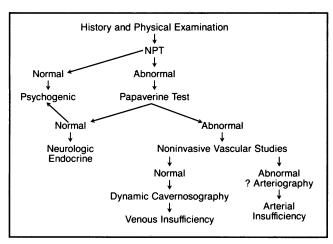


Figure 1.—The graph shows the protocol used at the Northwest Center for Impotence, Bellevue, Washington, to evaluate male sexual dysfunction. NPT = nocturnal penile tumescence

rapid filling of internal and external pudendal venous systems and the prostatovesical plexus. After infusion of a saline solution or artificial erection with the use of papaverine, occlusion of venous return is seen in normal subjects, but not in cases with measurable degrees of venous insufficiency.⁷

Neurologic Assessment

A thorough general neurologic examination is carried out with special attention to specific aspects of sacral innervation. On occasion, formal urodynamic studies and sacral reflex latency time determinations have been done in collaboration with the hospital electroencephalographic laboratory. Abnormal sacral neurologic function in cases such as multiple sclerosis, diabetes mellitus or chronic back syndromes are denoted by latency times of greater than 45 milliseconds. Dorsal penile nerve sensory function has been additionally assessed through routine biothesiometer testing of vibratory sensation as described by Levine and Sax. 9

Psychosocial Assessment

Psychologic evaluations are conducted by the clinic coordinator or collaborating certified psychologist-psychiatrist personnel. Before referral for psychologic assessment, a Minnesota Multiphasic Personality Inventory profile has occasionally been done. Selected patients have been put on short-term counseling, sex therapy or formal psychotherapy programs. A protocol has also been developed to evaluate the efficacy of papaverine-phentolamine injection therapy coupled with psychotherapy for well-selected psychogenically impotent patients. This study will be the subject of a future report.

Nocturnal Penile Tumescence Studies

Evaluation of nocturnal penile tumescence testing is routinely done either with snap-gauge testing or by take-home monitoring with the Rigiscan tumescence and rigidity monitor. When results of snap-gauge screening have been inconclusive or greater definition is required, Rigiscan monitoring for one or two nights has been successfully used. Concurrent tumescence and rigidity measurements have been achieved without the need of extensive laboratory testing or technician monitoring. The Rigiscan data logging unit has been used in conjunction with a software program operated through an IBM PC microcomputer for processing and printing data.

Each nocturnal event is graphically displayed to allow evaluation of both penile tip and base tumescence and rigidity over time. 12

Results

Patients have been categorized into four diagnostic groups: organic, primary organic, psychogenic and primary psychogenic.

Organic

Organic impotence has been defined as a lack of maximal or partial rigid erection preventing vaginal penetration, associated with identifiable medical causes. Prominent psychologic factors are absent and nocturnal penile tumescence testing has been confirmatory.

Primary Organic

In this category, some variability and discrepancy of nocturnal penile tumescence test results have been noted, with relevant psychologic factors having been present. The organic medical condition or treatment is considered predominant, however, as the cause of erectile failure.

Psychogenic

In this situation, erectile activity sufficient for penetration has been seen with nocturnal tumescence testing, and psychosexual evaluation has elicited a notable predominance of psychological factors.

Primary Psychogenic

Psychologic factors are considered preeminent in this category, but are coupled with organic disease of lesser importance to the erectile dysfunction.

Of the total group of 300 patients, 149 (50%) had organic processes, 28 (9%) organic disease with associated psychologic contributions, 94 (31%) purely psychogenic causes and 29 (10%) had psychogenic predominance coupled with organic diatheses of lesser importance (Table 1). Ages in the series ranged from 25 to 85 years, with organic diagnoses increasing with age, peaking in the 60- to 69-year age group. Considerable psychogenic impotence was seen in older age groups as well. In all, 39% of patients were single. Psychogenic causes were twice as common in the single group.

Organic Impotence

Organic causes of impotence are outlined in Table 2. A predominance of vascular-related, neurologic and endocrine disorders has been seen. Penobrachial indices are lowest in vascular, diabetic, postsurgical and trauma cases. The diabetic case incidence is only 7%, lower than that reported in most series. ¹³ Relative to the incidence, however, the rate of penile implantation was quite high in this group (Table 3).

Psychogenic Impotence

Thus far, 55 patients have received counseling, 18 have been referred for sex therapy and 6 have initiated significant psychotherapy programs. During clinical evaluation it has been found that patients with persistent impotence ultimately display psychologic manifestations even if physical factors predominate. In addition, psychogenic factors persist after organic disease is treated. Even in apparently obvious psychogenic cases, subtle organic factors can be etiologically relevant.

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Penile Vascular Studies

Penile vascular studies were done on 203 patients and included plethysmographic recordings of penile pulse volume, photoplethysmographic and Doppler penile blood flow determinations with penobrachial index calculations. The PBI decreased progressively with increasing age. An excellent correlation existed in this series between Doppler PBIs lower than 0.72 and abnormal pulse volume recordings. Photoplethysmography was more sensitive than Doppler for PBI determinations but carried a higher false-positive rate. Doppler penile pressure measurements were technically not obtainable in all patients, however. Rarely is the penobrachial index obtained by photoplethysmography higher than the Doppler PBI; consequently, if the PBI by photoplethysmography is greater than 0.76, a Doppler study is not required. Photoplethysmography and pulse volume recordings are reliable and somewhat more convenient to do than Doppler recordings, but data must be interpreted collectively in assessing overall penile vascular status.

Nocturnal Penile Tumescence Studies

Snap-gauge testing and Life-Tech or Rigiscan nocturnal penile tumescence monitoring were used. Of the total series, 63% were tested with some form of penile tumescence monitoring (Table 4). Of the evaluated group (191 patients), 56% had screening accomplished with the snap-gauge device and 46% by nocturnal penile tumescence monitoring. An overlapping group of 8% was tested by both techniques. Snapgauge testing as an isolated measure of rigidity was useful with relatively acceptable correlations for both organic and psychogenic cases. An organic false-positive rate of 20% was obtained, however; the psychogenic false-negative rate was a more acceptable 4%. A snap-gauge accuracy of 96% for psychogenic cases and 80% for organic causes was noted

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Diagnostic Group	Number	Percent
Organic	149	50
Primary organic		9
Psychogenic		31
Primary psychogenic	29	10
Total	7 1 2 1 1 TOTAL	100

Patients .			
	Number	Percent	Average PBI
Vascular	49	16	0.59
Neurologic	27	9	0.81
Diabetes mellitus	20	7	0.69
Endocrine	17	6	0.79
Drug related		2	0.83
Venous insufficiency		5	0.80
Peyronie's disease		2	0.90
Postsurgical		2	0.69
Posttraumatic		1	0.62
Infection	2	1	0.89
Primary organic	28	9	0.73
Total	177	60	

(Table 5). Nocturnal penile tumescence monitoring data displayed an organic false-positive rate of 22% and a psychogenic false-negative rate of 8%. Therefore, the accuracy of penile tumescence monitoring with psychogenic cases was 92% and 78% for organic cases (Table 5).

Diabetes mellitus 3 2 1 6 Vascular 4 2 1 7 Peyronie's disease 2 0 1 3 Postsurgical 0 0 1 1 Posttrauma 2 0 0 2 Neurogenic 3 1 0 4 Mixed 4 0 2 6	Cause of Impotence	Inflatable	Malleable	Hydroflex	Total
Peyronie's disease 2 0 1 3 Postsurgical 0 0 1 1 Posttrauma 2 0 0 2 Neurogenic 3 1 0 4	Diabetes mellitus	3	2	1	6
Postsurgical 0 0 1 1 Posttrauma 2 0 0 2 Neurogenic 3 1 0 4	Vascular	4	2	1	7
Posttrauma 2 0 0 2 Neurogenic 3 1 0 4	Peyronie's disease	2	0	1	3
Neurogenic	Postsurgical	0	0	1	1
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Mixed 4 0 2 6	Neurogenic	3	1	0	4
	Mixed	4	0	2	6

TABLE 4.—Percentage Having Nocturnal Penile Turnescence Studies, N=191

	Patients		
Test	Number	Percent*	
Snap gauge	 . 107	56	
Monitor	 . 88	46	

TABLE 5.—Nocturnal Penile Turnescence (NPT) Testing Results *

	Snap Gauge		
		Test Results	
Patient Group	Positive	Partial	Negative
Organic	3	15	43
Primary organic	2	6	5
Psychogenic	17	7	1
Primary psychogenic	<u>.</u> <u>2</u>	_6	_1
Totals	24	34	50
	NPT Monitor		
Patient Group	Normal (Pos)	Borderline	Abnormal (Neg)
Organic	4	3	42
Primary organic	2	2	6
Psychogenic	17	3	0
Primary psychogenic	<u>4</u>	_1	_4
Totals	27	9	52

"In these studies, a "positive" result indicates a normal test; a "negative" result indicates the presence of an abnormality.

TABLE 6.—Drugs	Used in Medical Treatment of Impotence	*
		_

Drug		Patients, No.
Isoxsuprine hydroc	hloride (Vasodilan)	44
	Halotestin)	
	nate (Depo-Testosterone)†	
Papaverine hydroc	hloride‡	53

^{*}Some patients received more than one drug. †Administered intramuscularly. ‡Administered intracorporeally.

Neg=negative, Pos=positive

Testos	terone Give	n Orally (N=10)		
Diagnostic Group	Patients, No.	Serum Testosterone Level, Range, ng/dl	Average PBI	Results*
Organic	7	249 to 373	0.80	+(5) -(2)
Primary organic	1	359†	0.66	±(1)
Psychogenic	1	328†	0.87	-(1)
Primary psychogenic	1	439†	0.88	-(1)
Testosteror	ne Given Int	ramuscularly (N=50)		
Organic	22	67.5 to 400	0.74	+(16) ±(2) -(4)
Primary organic	18	190 to 384	0.77	+(8) ±(2) -(8)
Psychogenic	3	468 to 532	0.81	+(1) -(2)
Primary psychogenic	7	230 to 398	0.78	+(4) ±(3)
PBI=penobrachial index, +=posi	tim	ativo 4 ocuinocal		

	Isoxsuprine Hy	drochlo	ride Therapy (N=44)		
	Pa Diagnostic Group	ntients, No.	Testosterone Level, Range, rig/dl	Average PBI	Results
	Organic	25	247 to 820	0.62	+(4) ±(4) -(17)
	Primary organic	7	284 to 612	0.72	+(4)
2	Psychogenic	1		0.95	–(1)
	Primary psychogenic	11	325 to 830	0.78	+(5) ±(4) -(2)
	Yohiml	oine The	rapy (N=18)		
	Organic	3	339 to 473	0.77	-(3)
	Primary organic	2	509 to 612	0.68	-(2)
	Psychogenic	12	325 to 726	0.86	6/12+
	Primary psychogenic	1	511	0.75	±(1)

TABLE 9.—Intracorporeal Pharmacologic Therapy, N=53*

Papaverine hydrochloride, 30 mg, + phentolamine mesylate, 0.83 mg 1 ml or less administered

- 2 ×/wk or 10 ×/mo
- Careful monitoring and follow-up with liver function tests
- Observe for hematuria, infection, priapism
- Need extensive informed consent

*The following response to the rapy was noted: 62% responders, 17% partial responders, 21% nonresponders.

TABLE 10.—Complications of Penile Implant Therapy (N=29)

		Type of Implai	nt	
Complication	Inflatable	Hydroflex	Malleable	
Loose connectors	2			
Pump malfunction	1			
Cylinder herniation	1			
Hematoma	2	0	0	
Infection	1	0	0	

Sacral Reflex Latency Testing

Selected patients had sacral reflex latency testing with fairly conclusive results—that is, latency times greater than 45 ms. Sensory threshold monitoring of vibratory appreciation has recently been tested routinely with the biothesiometer. According to Goldstein, useful information can be obtained in cases of a dorsal penile neurosensory deficit (I. Goldstein, MD, Department of Urology, Boston University School of Medicine, oral communication, 1985).

Hormone Determinations

Prolactin values were measured frequently, but were elevated on only two occasions, with no significant pituitary disease present on follow-up testing. Repeat determinations of testosterone levels of patients taking androgens by mouth consistently showed further reductions of already low testosterone values, thought to be on the basis of biofeedback suppression of gonadotropins and endogenous testosterone production, together with the concurrent presence of androgenic metabolites other than testosterone.

Medical Therapy

Medical treatments used at the center are noted in Table 6. Oral and intramuscular administration of androgen provided optimal results, with complete responses of 60% and 48%, respectively (Table 7), but overall numbers are small. A complete response rate to the use of isoxsuprine hydrochloride is low (29%) and unpredictable. Giving yohimbine provided no benefit in patients with organic problems, but it was of significant short-term benefit (38%) to patients with psychogenic causes, suggesting a strong placebo effect (Table 8). Results with the use of combinations of yohimbine and isoxsuprine have also been unimpressive.

The most notable medical therapy has been with the administration of papaverine and phentolamine intracorporeally. In all, 53 patients have been treated for periods of as long as a year with a 62% complete response rate, partial response 17% and no response 21% (Table 9). Iatrogenic priapism has been reversed on four occasions with corporeal irrigation and injections of dilute α -metaraminol solution. Papaverine therapy has been discontinued in two patients who had cavernosal or tunical focal fibrosis. A focal necrotic superficial eschar of the glans penis developed in one patient after injection and the drug therapy was discontinued.

In cases of impotence related to cardiac drug usage, dosage adjustments or a switch to more optimal drugs is coordinated with referring physicians. Smoking cessation, reducing alcohol consumption and other beneficial life-style changes are strongly advocated.

Surgical Therapy

Of the 300 patients, 29 (10%) received penile implants with either Malleable, Hydroflex and AMS or Mentor inflatable penile prostheses. The age range was 33 to 75 years, with a peak incidence of implantation occurring between 50 and 70 years of age. Patients having a vascular cause constituted the largest single group. One venous ligation procedure was accomplished with inconclusive results, but no penile revascularizations were done. As an adjunct to surgical treatment, on occasion the surgical isolation bubble system has been used with good results. ¹⁴ The surgical complication rate was low, with specific adverse events noted in Table 10.

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Discussion

There are numerous advantages inherent in providing a multidisciplinary approach for the treatment of impotence. Prompt, coordinated evaluation of both organic and psychogenic factors can be initiated in a unified care setting. The relative importance of certain factors can be best ascertained with the close collaboration of and communication with involved urologists and such persons as consulting endocrinologists, psychiatrists and psychologists. 15,16 A framework for clinical research projects and data analysis can also be provided. Networking with similar groups throughout the country is feasible. Patients and their families have been quick to recognize the level of interest and support provided and respond accordingly. The most optimal situation involves close physical proximity of health care professionals in a center, although successful operations are possible among dispersed personnel.

The role of clinic coordinator cannot be overemphasized. This person provides an initial contact point and in many respects sets the necessary tone for successful ongoing relationships. Adjunctively, a full spectrum of educational audiovisual materials is crucial to enhancing patient levels of awareness and understanding, coupled with reinforcing discussions with center personnel. Clinic coordination with patient support groups has also been influential in the context of the overall program.

Penovascular studies can be helpful in assessment and have been used with increasing frequency by many investigators.²⁻⁴ They have been accurate and of diagnostic benefit when interpreted selectively.

The selected use of Rigiscan testing has provided considerable current refinements to nocturnal tumescence testing. The take-home monitor system is cost-effective and adaptable to the clinic setting. Considerable assistance has been noted when interpreting findings suggesting venous insufficiency, uncoupling or dissociation. It is important to interpret an entire tracing sequence rather than focusing on single indices such as maximal rigidity.

Nocturnal penile tumescence testing can show individual and methodologic differences and therefore cannot be used as the sole determinant for differentiating organic from psychogenic impotence. But it has been a good screening tool. Rigiscan testing has overcome the nonlinearity problem seen with other available nocturnal tumescence monitors.

During the course of clinic evaluations and therapeutic trials, certain treatment methods have shown greater promise. The selected use of injectable or oral androgens is supported by available data in this study. Firm conclusions cannot be reached regarding such drugs as vohimbine and isoxsuprine. for they are of unpredictable benefit. Papaverine injection therapy continues to show short-term promise without a major risk of side effects. Of particular interest is the multiplicity of applications for papaverine therapy. The technique has been used diagnostically to differentiate cases of venous insufficiency and therapeutically to "prime the pump" in conjunction with psychotherapy. In its more standard application, papaverine injection therapy has provided substantial benefit for the management of neurogenic impotence, mild to moderate arterial vasculogenic impotence and mild cases of penile venous insufficiency.

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